REMARKS

Claims 95, 96 and 101-104 are currently pending. Claims 95 and 101 have been amended. Specifically, claims 95 and 101 have been amended to provide appropriate references to the amino acid residues of the sequence identifiers (SEQ ID NOs). No new matter has been added.

Priority

According to the Examiner, support is not found for the recited portion, species J - Fel 31-1 (residues 33-59 of SEQ ID NO:6). The Examiner points out that "Fel 31-1 appears to be epitope 14-40 as denoted in the figure." The Examiner concludes that "the recitation of such portions or epitope containing portions are not apparently supported from the specification as filed in 1990. Accordingly, support and priority within the previous publications is not found, particularly for this species and therefore the effective filing date awarded instant claims is that of the instant filing date of 9-15-00 absent evidence for support."

As described above, Applicants have amended the claims to provide the appropriate references to the amino acid residues of the sequence identifiers (SEQ ID NOs). In particular, the previous and incorrect residue numbers erroneously took into account the residues comprising the leader sequence. No new matter has been added.

Accordingly, support for the pending claims can be found in the parent application, PCT/US90/06548 (filed Nov. 2, 1990). Therefore, Applicants respectfully request the present application be awarded its claim of priority to PCT/US90/06548.

Double Patenting

Claims 95, 96 and 101-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,019,972 and over claims 1-24 of US Patent No. 5,547,669. Upon an indication of allowable claims in the pending application, Applicants will file a terminal disclaimer, if appropriate.

Rejection of Claims 95, 96 and 101-104 Under 35 USC § 112, First Paragraph

Claims 95, 96 and 101-104 are rejected as failing to comply with the written description requirement. Based on the foregoing claim amendments, and Applicants' comments with respect to priority (above), Applicants respectfully request that this rejection be withdrawn.

Rejection of Claims 95, 96 and 101-104 Under 35 USC § 102(b) and (e)

Claims 95, 96 and 101-104 are rejected under 35 USC § 102(b) and (e) as being anticipated by U.S. Patent Numbers 6,019,972 and 5,547,669 (cumulative references). Based on the foregoing claim amendments, and Applicants' comments with respect to priority (above), Applicants respectfully request that this rejection be withdrawn.

Rejection of Claims 95, 96 and 101-104 Under 35 USC § 102(b) and (e)

Claims 95, 96 and 101-104 are rejected under 35 USC § 102(b) as being anticipated by Leiterman *et al.*, as evidenced by UniProt_03 alignment with accession no. P30440, and as further evidenced by Harlow & Lane Cold Spring Harbor Labs (1988, p. 427). According to the Examiner:

> Leiterman *et al.* teach cat allergen 1: biochemical, antigenic and allergenic properties. In particular the therapeutic composition of protein is provided in isolated form. The peptide is a part of a multi protein complex of various MW isoform . . . comprised therefore of a mixture. A peptide and its properties are inseparable, accordingly the peptide has the properties as noted in claim 102, the products being the same. Claims 1-3-104 are directed to product by process limitations and therefore do not distinguish over the peptide product. Harlow & Lane further teach that epitopes may be of only 4 or 5 amino acid . . . The accession notes identify in amino acid sequence in addition to the epitope of residues 31-57 corresponding with 100% identity to epitope of SEQ ID NO:6 residues 33-59. Thus, the reference teachings anticipate the claimed invention.

Applicants respectfully traverse this rejection. The claims are drawn to "isolated" polypeptides having specified amino acid sequences and compositions comprising such polypeptides. As defined in the present specification (see, *e.g.*, page 2, lines 27-35 and page 8, lines 9-10), the term isolated "refers to the TRFP protein or peptides free of all other cat polypeptides or contaminants."

In contrast, Leiterman *et al.* describe "partial purification of cat allergen 1" (see, e.g., the abstract and page 152, second column, first full paragraph). Accordingly, the protein components taught by Leiterman *et al.* ***are clearly not free of all other house dust mite proteins*** as claimed. Applicants emphasize the long history of case law which firmly establishes the principle that ***purity which imparts practicality and/or usefulness to a protein can be the basis for novelty and patentability of the protein.*** For example, the following cases are particularly applicable and on point with the facts of the present case.

In the cases of *Merck v. Olin Mathieson Chemical*, 155 USPQ 139 (4th Cir. 1958); and *Merck v. Chase Chemical*, 155 USPQ 139 (D.N.J. 1967), it was held that claims covering purified vitamin B-12 protein were patentable over the same protein contained in impure form in liver extracts. In each case, the claimed purified vitamin B-12 proteins were deemed patentable based on their level of purity which the court held made them *"different from the natural composition."*

Similarly, in *In re Bergstrom*, 166 USPQ 256, 262 (CCPA 1970) the court held that pure prostaglandin compounds, PGE_2 and PGE_3, were patentable over the same compounds in impure form. The court explicitly stated that:

> [T]he fundamental error in the board's position, as we see it, is the analysis and answer it gave to the sole issue it accurately posed - 'whether the claimed pure materials are novel as compared with the *less pure* materials of the reference' (emphasis added). It seems to us that the answer to that question is self evident: ***by definition, pure materials necessarily differ from less pure or impure materials*** and, if the latter are the only ones existing and available as a standard of reference, as seems to the be situation here, perforce the 'pure' materials are 'new' with respect to them (emphasis added).

Moreover, the court's holding was based on the observation that:

> [W]hat appellants claim - pure PGE_2 and pure PGE_3 - ***is not 'naturally occurring'*** (emphasis added). Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, *or* what has previously been known to exist. (Emphasis in original). *Id.* at 261-262.

The patentable distinction between naturally occurring, impure, proteins versus the same proteins in purified form was further examined in *Ex parte Stern*, 13 USPQ2d 1379 (BPAI 1989). In this case, the issue was patentability of human interleukin 2 (IL-2) "purified to homogeneity" over human IL-2 in partially pure form. It was the Examiner's position that the claimed purified, homogenous protein was not patentably because "...the degree of purity alone is not sufficient to warrant a patentably distinct protein,...". *Id.* at 1381.

On appeal, the Board reversed the Examiner's rejection, stating that:

> We are not familiar with any jurisprudential precedent which supports the examiner's sweeping statement... It is clear from the record and appreciated by

> the examiner that IL-2 is known to enjoy biological activity in the treatment of patients afflicted with tumors. Conventional methods of obtaining IL-2 result in a 'soup' containing IL-2 in minute quantities together with various cogenerated proteins. Skilled workers in this particular art have sought to purify IL-2 to homogeneity and apparently have not succeeded. Against this background, ***the examiner's cavalier disposition of the degree of purity expressed in the appealed claim is completely unrealistic and clearly erroneous.*** *Id.* (emphasis added)

In sum the above-discussed cases clearly establish that purity ***can be a basis for patentability***. As held in these cases, the fact that the instantly claimed isolated TRFP peptide is free of all other house dust mite proteins makes it "***necessarily differ***" from peptides in impure form (*In re Bergstrom, supra.*). Moreover, based on the increased ***practicality*** and ***usefulness*** as the claimed polypeptides which are free of all other cat proteins and contaminants, combined with a lack of teaching or suggestion in the prior art as to how to achieve such a level of purity, or reasons why one would want to achieve such a level of purity, the claimed polypeptides and compositions are both novel and unobvious over the teachings of the cited reference. Indeed, the use of the claimed highly pure polypeptides, which are free of all other cat proteins, provides the advantage of minimizing the risk of occurrence of anaphalylactic reactions due to protein contaminants following administration in immunotherapy. Therefore, the purity of the claimed peptide imparts both practicality and usefulness (*e.g.*, increased safety) upon the peptide.

Moreover, in view of the ***vast*** number of TRFP peptides which could have been chosen and tested for use in a therapeutic composition, Leiterman *et al.* fail to teach or suggest the particular epitope-containing peptides encompassed by the claims. Therefore, without such a teaching, the claimed peptides are novel and patentable.

CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting the prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,

By _____

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